

### **Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the captioned application:

#### **Listing of Claims:**

Claims 1-28 (cancelled).

:Claim 29 (currently amended): A solid dosage unit comprising a compressed admixture of a proportionate amount of simethicone, and an adsorbent selected from the group consisting of magnesium aluminometasilicate, and silicified microcrystalline cellulose, wherein the proportionate amounts, by weight, in the admixture of simethicone, magnesium aluminometasilicate, and silicified microcrystalline cellulose is about 1: about 0.5 to about 0.85 : about 0.9 to about 1.30 per solid dosage unit.

Claim 30 (previously presented): A solid dosage unit of claim 29, further comprising at least one additional active ingredient.

Claim 31 (currently amended): A solid dosage unit of claim 30, ~~wherein~~ wherein the active agent is selected from the group consisting of bisacodyl, famotidine, prucalopride, diphenoxyate, loperamide, lactase, mesalamine, bismuth, and pharmaceutically acceptable salts, esters, isomers, and mixtures thereof.

Claim 32 (currently amended): A solid dosage unit of claim 21, wherein the active agent is loperamide, or pharmaceutically acceptable salts, esters, or isomers thereof.

Claim 33 (previously presented): A solid dosage unit of claim 32 having at least 34 wt% simethicone.

Claim 34 (previously presented): A solid dosage unit of claim 33 having from about 35 wt to about 54 wt% simethicone.

Claim 35 (previously presented): A solid dosage unit of claim 29 having from about 19 wt% to about 29 wt% silicified microcrystalline cellulose and from about 31 wt% to about 39 wt% magnesium aluminometasilicate.

Claim 36 (previously presented): A solid dosage unit of claim 35 having from about 23 wt% to about 27 wt% silicified microcrystalline cellulose and from about 33 wt% to about 37 wt% magnesium aluminometasilicate.

Claim 37 (previously presented): A solid oral dosage form of claim 29, wherein the compressed admixture is a tablet having a hardness value of at least 2 kp/cm<sup>2</sup>.

Claim 38. (previously presented): A solid oral dosage form of claim 37, wherein the compressed admixture is a tablet having a hardness value of from about 5 to about 10 kp/cm<sup>2</sup>.

### **REMARKS**

Claim 29 has been amended in view of the Examiner's suggested amendments in Paper No. 12202006 at pages 2-3. In addition, claim 31 was amended to remove an inadvertent space in the term "wherein" and claim 32 was amended to remove an extra space before the term "active."

It is submitted that no new matter has been introduced by the foregoing amendment. Approval and entry of the amendments is respectfully solicited.

### **Objection**

Claim 31 was objected to for containing an "informality." (Paper No. 12202006 at 2.) As noted above, claim 31 has been amended to remedy the deficiency in the term "wherein" and, it is submitted, the objection is rendered moot and should be withdrawn

### **Indefiniteness Rejection**

Claim 29-38 were rejected under 35 USC §112, second paragraph for the following reasons:

Independent claim 29 recites that an adsorbent is selected from the group consisting of magnesium aluminometasilicate and silicified microcrystalline cellulose. According to the claimed language, the final composition of the claimed invention could only contain single adsorbent selected from magnesium aluminometasilicate or silicified microcrystalline cellulose, not both.

Since the criticality of the instant application lies in the specific proportionate amounts of simethicone:magnesium aluminometasilicate:silicified microcrystalline cellulose, about 1: about 0.5 to about 0.85:about 0.9 to about 1.30 per solid dosage unit, in said composition, the final composition resulted from the selection of single adsorbent, not mixture of aluminometasilicate and silicified microcrystalline cellulose, leaves the reader in doubt as to the meaning of the invention to which they refer, thereby rendering the definition of the subject-matter of said claims unclear.

With respect to claims 37 and 38 (which is dependent claim of claim 37), there is insufficient antecedent basis for "the compressed admixture" in the independent claim 29. (Paper No. 12202006 at 3-4.)

For the reasons set forth below, the rejection is respectfully traversed.

Claim 29 was amended in view of the Examiner's suggested claim language at pages 2-3 of Paper No. 12202006. It is believed that the amendments to claim 29 render the instant rejection moot. Therefore the rejection should be withdrawn.

Finally, the Examiner is invited to call the applicants' undersigned representative if any further action will expedite the prosecution of the application or if the Examiner has any suggestions or questions concerning the application or the present Response. In fact, if the claims of the application are not believed to be in full condition for allowance, for any reason, the applicants respectfully request the constructive assistance and suggestions of the Examiner in drafting one or more acceptable claims pursuant to MPEP § 707.07(j) or in making constructive suggestions pursuant to MPEP § 706.03 so that the application can be placed in allowable condition as soon as possible and without the need for further proceedings.

Accordingly, entry of the claims and allowance of the claims is respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

Respectfully submitted,

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